

We are your ophthalmic treatment development solution, from lead candidate selection to clinical proof of concept, and beyond. We offer expert, fully integrated, comprehensive solutions across the relevant services to ensure your ophthalmic drug gets to market, fast.

## PRECLINICAL SAFETY TESTING

- 50 years of experience — no study ever rejected for reasons of design, conduct, or data integrity
- Broad solutions offering across dosing routes and specialized techniques
- On-site Diplomate, American College of Veterinary Ophthalmologists (DACVO)
- Significant investment in specialized equipment like OCT and Retcam

## FORMULATION, MANUFACTURING, AND ANALYTICAL SERVICES

- Seamless transition from proof-of-concept formulations to clinical manufacturing
- Potent compounds and controlled substances
- Class C Manufacturing suites for development and clinical/commercial batches
- Flexible filling options, including vials, droppers, and custom containers
- Scale options from small batches up to 400L
- Milling capabilities for micro- and nanosuspension products
- Expert analytical support for method development, validation, and ICH stability testing

## REGULATORY AND SCIENTIFIC AFFAIRS

## CLINICAL RESEARCH SERVICES

- In-house ophthalmologist with over 20 years of experience
- Three North American inpatient units (from coast to coast) with over 500 beds — fully equipped inpatient and outpatient capabilities
- Robust network of ophthalmology sites in close proximity to our clinics
- FIH to Phase IIa focused, more than 40 ophthalmology trials completed
- Database of over 400K participants for healthy normal and patient recruitment

## BIOANALYTICAL SERVICES

- Strong, in-house ocular bioanalytical scientific expertise
- State-of-the-art instrumentation to achieve low limits of quantitation for systemic exposure
- Expertise working with rare and limited matrices such as tears

## REGULATORY APPROVAL EXPERTISE FOR PRODUCTS, PREPARATIONS, AND MEDICAL DEVICES:

- Briefing documents and support for all types of global regulatory meetings, including:
  - Health Canada
    - Pre-CTA gap analysis
    - Pre-CTA package preparation and Health Canada meeting support
  - FDA
    - Pre-IND gap analysis
    - Pre-IND briefing package preparation and FDA meeting support
    - IND preparation and submission
    - Investigator's Brochure preparation
- CTA preparation, submission, and maintenance
- Nonclinical and clinical regulatory strategy
- Toxicology consulting and strategic advice

Our experts are always fully informed about the most recent regulatory guidances, ensuring that your program stays on track.

## STATE-OF-THE-ART BIOANALYTICAL CAPABILITIES:

- Preclinical and clinical studies
- Large and small molecules

Bioanalytical scientists work hand in hand with study directors to ensure appropriate handling of samples for all your studies. We have equipment and assay platforms that provide the ultra-low sensitivity necessary for plasma or serum TK/PK samples for ocular drug development.

## PRECLINICAL SAFETY TESTING:

- All ophthalmic therapeutic indications
- Experience with many different types of formulations including nanoparticles and ocular implants
- All ophthalmic routes of administration
- Studies ranging from single dose acute to six- and nine-month duration
- Ocular pharmacokinetic studies in multiple routes and species.

We will get your program off on the right foot, and rapidly advance to clinical trials.

## CLINICAL PHARMACOLOGY UNITS ROUTINELY ACCOMMODATE:

- Topically administered ophthalmic medications
- Healthy normal participants or patients
- Broad network of ophthalmology research centers, including key opinion leaders and principal investigators
- Experts using the latest equipment to perform many ophthalmological procedures

For trials involving devices, surgical assessments, or other highly specialized procedures, we review requirements on a case by case basis to ensure the best fit for your program.

## HIGH QUALITY FORMULATION, MANUFACTURING, AND ANALYTICAL SERVICES:

- All ophthalmic products, including potent compounds and controlled substances
- Liquids, gels, injectables, or capsules
- Formulation development to commercialization
- Analytical method development through validation and ICH stability testing

Our CDMO capabilities support your development program, from the clinic to market, with state-of-the-art manufacturing, analysis, and packaging of your ophthalmic therapeutic.

